

Section IV. Guidance Documents**Chapter II. Growing Areas**

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.03 Sanitary Survey and the Classification of Growing Waters

NSSP guidance documents provide the public health principles supporting major components of the NSSP and its Model Ordinance, and summaries of the requirements for that component. NSSP Model Ordinance requirements apply only to interstate commerce although most states apply the requirements intrastate. For the most up to date and detailed listing of requirements, the reader should consult the most recent edition of the Model Ordinance.

Oysters, clams, mussels and scallops are filter feeders that pump large quantities of water through their bodies when actively feeding. During this process, molluscan shellfish can concentrate microorganisms, toxigenic micro-algae and poisonous or deleterious substances from the water column when they are present in the growing waters (Kennedy *et al.*, 1996). Concentrations in the shellfish may be as much as 100 times that found in the water column. If human pathogens are concentrated to an infective dose, and if the shellfish are consumed raw or partially cooked, human disease can result. If toxigenic micro-algae are present and producing toxin, human illness or death can occur, and cooking is not reliable as an effective barrier against intoxication.

The goal of the NSSP is to control the safety of shellfish for human consumption by preventing harvest from contaminated growing waters. In implementing this concept, the NSSP uses five classifications for growing areas: approved, conditionally approved, restricted, conditionally restricted, and prohibited. The placement of a growing area in any one classification is based upon the growing area's conformance with the requirements established for that classification. Conformance with a classification's requirements is established through the sanitary survey.

The positive relationship between sewage pollution of shellfish growing areas and disease has been demonstrated many times (Rippey [a] and [b], 1994). Shellfish-borne infectious diseases are generally transmitted through a fecal-oral route (i.e., the shellfish become contaminated by sewage and are eaten by humans). The pathway can be quite circuitous. The cycle usually begins with fecal contamination of the growing waters. Feces deposited on land surfaces can release pathogens into surface waters via storm water runoff or collected wastes can be discharged directly into a waterway. The runoff or discharge may go directly into the growing area or indirectly as is the case with wastes transported by freshwater streams to estuarine or marine waters. Information concerning the relationship between sewage pollution of bivalve shellfish growing areas and human disease is available in several good summaries (Hackney and Potter 1994 [a] and [b]; Jaykus *et al.*, 1994; Stelma and McCabe, 1990).

Epidemiological investigations of shellfish-caused disease outbreaks have found difficulty in establishing a direct cause and effect between a numerical correlation and pollution source strength, bacteriological quality of water, and the degree of hazard to health. Tidal fluctuations and pollution source variations contribute to a high degree of variability in water quality. Investigations made from 1914 to 1925 by the states and the Public Health Service, a period when disease outbreaks attributable to shellfish were more prevalent, indicated that typhoid fever or other enteric diseases would not ordinarily be attributed to shellfish harvested from water in which not more than 50 percent of the 1 cc (cubic centimeter) portions of water examined were positive for the coliform group (an MPN of approximately 70 per 100 ml),

provided the areas were not subject to direct contamination with small amounts of fresh sewage which could not be detected by bacteriological examination.

Following the oyster-borne typhoid outbreaks during the winter of 1924-25 in the United States (Lumsden, 1925), the National Shellfish Certification Program, now the National Shellfish Sanitation Program (NSSP), was initiated by the states, the Public Health Service, and the shellfish industry (Frost, 1925). The 1925 criteria for safe growing areas were stated as: (1) the area is sufficiently removed from major sources of pollution so that the shellfish would not be subjected to fecal contamination in quantities which might be dangerous to the public health, (2) the area is free from pollution by even small quantities of fresh sewage, and (3) bacteriological examination does not ordinarily show the presence of the coli-aerogenes group of bacteria in 1 cc dilutions of the growing area water. The collective application of these criteria was known as the sanitary survey, which was used to determine if an area was safe for shellfish harvesting for human consumption. These criteria were adopted in the United States in 1925. Reliance on these criteria and others to measure excess variability in water quality were combined together with sanitary reconnaissance (shoreline survey), hydrographic and meteorological considerations, and patrol of closed harvest areas has generally proven effective in preventing major outbreaks of disease transmitted by the fecal-oral route. For a complete discussion of the history of the NSSP, see the historical overview by David Clem (1994) and the NSSP Guidance Document, *History of the Interstate Shellfish Sanitation Program* (ISSC/FDA, 2002).

The ability of shellfish to concentrate chemical pollutants from water and sediment can lead to accumulation of these poisonous and deleterious substances to levels that constitute a public health hazard (Kurland *et al.*, 1960; Texas Dept. Of Health, 1977). These poisonous or deleterious substances may enter shellfish growing areas through industrial or domestic waste discharges, seepage from waste disposal sites, agricultural land, geochemical reactions, or naturally occurring toxigenic micro-algae (O'Connor and Beliaeff, 1995; Liston, 1994). The degree to which these substances are concentrated depends upon such variables as the species of shellfish, water temperature and salinity, the level of contaminants in the waters, and the physiological conditions of the shellfish (Capuzzo, 1996; Roderick and Schneider, 1994; Rosijadi, 1996). The potential public health hazard posed by these substances must also be considered in assessing the safety of shellfish growing areas.

For a full discussion of the public health risk associated with micro-toxigenic algae, see the NSSP Guidance Document, *Guidelines for Developing a Marine Biotxin Contingency Plan* (ISSC/FDA, 2002).

Components of the Sanitary Survey

A review of epidemiological investigations of disease outbreaks attributable to the consumption of bivalve shellfish reveals that three general situations occur in the contamination of growing areas placed improperly in the approved classification. First, improperly conducted or outdated sanitary surveys or misapplication of water quality data have unwittingly allowed harvesting from sewage contaminated growing areas. Second, fresh fecal material present and not diluted, diffused, or not detected by ordinary bacteriological sampling procedures caused shellstock contamination (Lumsden, 1925). Dr. Gurion recognized the possibility of chance contamination as early as 1902 in his report on a typhoid outbreak:

"There is a zone of pollution established by the mere fact of the existence of a populated city upon the banks of a stream or tidal estuary which makes the laying down of oysters and clams in these waters a pernicious custom if persisted in, because it renders these articles of food dangerous at times, and always suspicious (Gurion, 1917)."

Third, shellfish illnesses have been traced back to areas where an intermittent pollution source contaminated the shellfish. Some of these areas could have been placed in the conditionally approved classification and managed to avoid harvest of polluted shellstock, provided the occurrences of the sources of pollution could be predicted and the boundaries of their effects determined. For a full discussion of the use of the conditional classifications, see the NSSP Guidance Document, *Management Plans for Growing Areas in the Conditional Classifications* (ISSC/FDA, 2002).

The first critical control point in preventing food-borne illness from shellfish consumption is identifying growing areas of acceptable sanitary quality. The completion of a sanitary survey is of paramount importance in making the distinction between acceptable and unacceptable growing areas, and is the key to accurate growing area classification as approved, conditionally approved, restricted, conditionally restricted, or prohibited. Under the NSSP Model Ordinance, a sanitary survey is required for each growing area prior to its approval by the state as a source of shellfish for human consumption or as a source for shellfish to be used in a depuration or relay operation. A sanitary survey is an in-depth evaluation of all environmental factors that have a bearing on the water quality in a shellfish growing area. The environmental factors include both actual and potential pollution sources, whether natural or man-made, and meteorological and hydrographic characteristics of the growing area. The principal components of a sanitary survey are: (1) identification and evaluation of the pollution sources that may affect the areas, (2) an evaluation of the meteorological factors, (3) an evaluation of hydrographic factors that may affect distribution of pollutants throughout the area, and (4) an assessment of water quality. For a complete discussion of the sanitary survey, see *Sanitary Surveys of Growing Waters* (Garreis, 1994).

(1) *An evaluation of the pollution sources that may affect the growing areas.* A pollution source survey (also known as a shoreline survey) must be conducted of the growing area shoreline and watershed to locate direct discharges (e.g., municipal and private sewage and industrial waste discharges, sewage package treatment units, malfunctioning septic tanks and animal manure treatment lagoons) and non-point sources of pollution (e.g., storm water runoff, and runoff from agricultural and wildlife areas). Municipal and industrial wastewater treatment facilities should be evaluated in terms of actual loading versus design capacity, type and concentration of pollutants discharged, effectiveness of their treatment processes and pollution control devices. For additional information concerning sewage treatment plant discharges and their control, see the NSSP Guidance Document, *Management Plans for Growing Areas in the Conditional Classifications* (ISSC/FDA, 2002) and the U.S. Environmental Protection Agency documents concerning increasing reliability of sewage treatment plants (USEPA [a] and [b], 1974).

The following survey procedures should be followed in the shoreline survey.

- *Survey Assignment*

Each shoreline survey area must be determined and assigned by the Authority. Each survey area must be identified by a unique designation. All survey data must be identified by this unique designation that allows for tracking of all forms used in the survey. All shoreline survey data must be documented and filed promptly.

- *Examination of Individual Properties for Pollution Sources*

* The boundaries of the shoreline survey area must be determined by an in-field investigation of the area topography and the proximity of individual properties to the growing area. Those properties with the potential to impact growing water quality must be included within the boundaries of the shoreline survey area. Once the boundaries of the shoreline survey area have been determined, all businesses and

residences must be examined and all potential discharges of wastes (raw sewage, kitchen wastes, laundry wastes, agricultural wastes, etc.) must be evaluated.

* The location of each property with a pollution source adversely impacting the growing area must be provided.

* If the property has a pollution source adversely impacting a growing area, one of the two notations listed below must be made concerning its impact on water quality.

a) Direct Impact: A pollution source having direct impact is defined as any waste discharge which has immediate impact on the growing area. An attempt should be made to quantify the volume of the discharge.

b) Indirect Impact: A pollution source having an indirect impact is defined as any waste discharge which reaches the growing area in a roundabout way. An attempt should be made to quantify the volume of the discharge.

* All sanitary, industrial, or agricultural pollution sources must be located on a map of the survey area.

* All animal farms must be evaluated. Evaluation must include the number and type of animals.

* All marinas must be evaluated in accordance with the requirements of the Model Ordinance.

* Notations must be made of any flocks of waterfowl and an estimation of their number given. Populations of wild animals such as deer and muskrat should be noted and where possible an estimation of their number given.

* Drainage ditches must be evaluated.

* Any other potential source of pollution, which in the surveyor's opinion might influence water quality, must be noted.

* At the end of each shoreline survey, the surveyor must write a summation. The surveyor must also provide a comprehensive map of the survey area identifying the location of each pollution source found.

The level of surveillance for poisonous and deleterious substances in a shellfish control program may vary widely. The intensity of the surveillance is frequently driven by a history of marine biotoxin contamination, sanitary survey findings, or findings from investigations by other state or federal agencies or academia. Review of existing background data derived from national and international monitoring programs can also be useful (O'Connor, 1996; Beliaeff *et al*, 1997). An assessment of possible sources in the sanitary survey should enable shellfish control program managers to determine if a potential problem exists and whether a need for further field study exists. Sampling for specific chemical contaminants in shellfish is recommended only when the pollution source survey reveals a potential problem, or if there is concern because of a lack of information.

When poisonous or deleterious substances are found in shellstock, the Authority must evaluate the levels that may be present against known tolerance levels in human foods or other appropriate information, and determine what action, if any, should be taken. Additional information concerning this topic can be found in the NSSP Guidance Documents: *FDA Action Levels, Tolerances and Other Values for Poisonous or*

Deleterious Substances in Seafood (ISSC/FDA, 2002); *Shellstock Relay* (ISSC/FDA, 2002); and *Guidance for Developing Marine Biotxin Contingency Plans* (ISSC/FDA, 2002). In the absence of specific tolerance or action levels, decisions must be made on a case-by-case basis using the best available knowledge.

(2) *An evaluation of meteorological factors.* Climate and weather can affect the distribution of pollutants or can be the cause of pollutant delivery to a growing area. Prevailing winds can determine the distribution of pollutants in a growing area. Rainfall patterns and intensity can affect water quality through pollutant delivery in runoff or cause flooding which can affect the volume and duration of pollutant delivery. An example of the effects of meteorology occurred in 1982. In the late fall, the arrival of cold fronts caused strong winds, abnormally low tides and high rainfall which resulted in raw sewage bypasses from overloaded sewage treatment plants. This combination of meteorological events resulted in raw sewage reaching a growing area causing shellfish-borne illness in 471 persons (Casper, 1982).

(3) *An evaluation of hydrographic factors that may affect distribution of pollutants throughout the area.* Examples of hydrographic factors are tidal amplitude and type, water circulation patterns, and the amount of fresh water. These factors, along with water depths and stratification caused by density (salinity and temperature) differences, and wastewater and other waste flow rates are used to determine dilution, and time of transport. Tracer dye studies provide site-specific dilution, dispersion and time of travel information, and can be used in calibration of site-specific hydrodynamic models.

(4) *An assessment of water quality.* In general, microbial reduction in seawater occurs by two different processes - physical dilution by advection and diffusion, and a process of biological inactivation. Dilution factors are physical and predictable with a direct relationship between pollution loads and dilution water available. The inactivation process is more variable and appears to be associated with the following factors: sunlight and solar radiation, absorption and sedimentation, temperature, predation, antibiosis, action of inorganic salts, nutrient deficiencies, the action of heavy metals and other substances, and effects of specific bacteriophage. Kator (1994) has provided a good summary of current knowledge concerning inactivation of bacteriological and chemical indicators caused by the effects of environmental factors.

Field and laboratory studies have demonstrated that enteric viruses can survive in marine water and shellfish from a few days to several months (Jaykus, 1994). In general, viruses survive longer at lower temperatures, at low salinity and when bound to sediments.

Evidence from many field studies indicates that a constant relationship does not exist between the bacterial pathogen, viral pathogen or coliform group levels in shellstock and the presence of these organisms in the overlying water column (Kator, 1994; Jaykus *et al*, 1994). Experience in the NSSP, however, has shown that shellstock from waters meeting the water quality standards for the approved classification are unlikely to be involved in shellfish-associated disease outbreaks attributed to fecal contamination of the growing area. In part, this is because the coliform group (total coliform) water quality standard of 70 MPN per 100 milliliters of growing water is equivalent to the fecal material contributed from one person diluted in about 2.27×10^8 liters (8 million cubic feet) of water free from the coliform group. Such a small amount of sewage reaching the growing area is likely to have been so treated, diluted, or aged that it will be of negligible public health significance.

The NSSP in its Model Ordinance allows for the Authority to classify a growing area using either a total coliform group or fecal coliform MPN standard as part of its sanitary survey. The two standards are believed to afford the same level of public health protection (Hunt and Springer, 1974). The NSSP Model

Ordinance further allows the application of either standard to different water bodies within the state. The NSSP Model Ordinance also recognizes two distinct water quality monitoring strategies to collect the total coliform group or fecal coliform monitoring data for application of the standards: Adverse pollution conditions are to be established for initial classification, but if no point source pollution source impact is found the systematic random sampling monitoring strategy can be used for monitoring. The Authority may adopt the use of both the total coliform group and fecal coliform standards and both monitoring strategies, if applicable, for each standard.

The difference between the adverse pollution condition monitoring strategy and the systematic random sampling monitoring strategy is determined by 3 factors:

- (1) The presence or absence of point source impact in the growing area;
- (2) The timing of water sample collection; and
- (3) The way in which the MPN data are calculated for comparison to the standard.

An adverse pollution condition (APC) is a state or situation, caused by meteorological, hydrological or seasonal events or point source discharges, that has historically resulted in elevated total coliform group or fecal coliform levels in a particular growing area. In using this monitoring strategy, sample collection must be timed to be representative of the major pollution impacts, since shellfish respond rapidly to an increase in the number of microorganisms in their surrounding waters. The APC monitoring strategy must be used in initial growing area classification to assess the impact by sewage treatment facilities, combined sewer overflows, or other point source discharges and to evaluate the impact of nonpoint pollution. The results of bacteriological sampling must be correlated with sewage treatment plant operation and evaluated in terms of treatment and nonpoint pollution contributions at the time of sampling. These results, combined with considerations for malfunctions, overloads, poor operation, and nonpoint triggering conditions are used in the initial classification.

The systematic random sampling monitoring strategy can be used in approved or restricted growing areas except those that are affected by point source pollution. This strategy assumes that monitoring conducted on a pre-established schedule at an adequate frequency will capture weather or rainfall conditions that trigger nonpoint pollution contribution. For a full discussion of this strategy, see the NSSP Guidance Document, *Systematic Random Sampling Monitoring Strategy* (ISSC/FDA, 2002).

Total coliform group or fecal coliform data collected under either the APC or the systematic random sampling monitoring strategy are reported as a MPN i.e. a statistical estimate of the number of bacteria per unit volume of water and is determined from the number of positive results in a series of fermentation tubes used in a particular laboratory test. A complete discussion of the MPN test can be found in *Standard Methods for the Examination of Water and Wastewater* (APHA, 1985). In the APC monitoring strategy, the application of the two-part water quality standards for both total coliform group and fecal coliform involves use of a median or geometric mean and a "percentage factor". The "percentage factor" corrects for the inherent variation of the MPN analytical method when used with a normally distributed data set. In the systematic random sampling strategy, the application of the two part water quality standards for both the total coliform group and fecal coliform involves use of a median or geometric mean and an estimated 90th percentile as the statistic to measure the variance of the data set. The use of the strategy requires that the times of samples be scheduled in advance, so monitoring runs are made with no consideration for meteorological conditions. For a more in-depth explanation, see the NSSP Guidance Document, *Systematic Random Sampling Monitoring Strategy* (ISSC/FDA, 2002).

A written sanitary survey report is needed to integrate the data from the pollution source survey, the hydrographic and meteorological investigations, and the water sampling into a comprehensive information analysis. The purpose of this analysis is to determine the appropriate classification for the growing area and the geographic boundaries of the classification. This report must include a compilation of relevant data, a water sample data analysis using appropriate data sorting to determine adverse pollution conditions and recognized statistical techniques, conclusions as to the appropriate growing area classification, and recommendations for necessary follow-up actions. The report may also consider relevant resource management, social, economic, or political factors that may influence the establishment of the classification boundaries, and the time periods for the open and closed status when conditionally approved and conditionally restricted classifications are proposed. Pollution conditions that cause closure, and conditions and time periods for seasonal openings must be included in the management plan.

Keeping the sanitary survey current consists primarily of routinely evaluating major pollution sources, collecting water quality data from sampling stations under the selected NSSP water quality monitoring strategy, and analyzing the data to assure that the classification continues to represent current sanitary conditions in the growing area. The sanitary survey must be repeated fully every 12 years. In the interim, the sanitary quality of each growing area must be reviewed as often as is necessary to ensure that the classification is appropriate. Certain sanitary survey components are required by the Model Ordinance to be updated annually and triennially (every third year). The growing area must be subjected promptly to a more intense and comprehensive sanitary survey reevaluation when monitoring or other information reveals a substantial change in the sanitary conditions. A reevaluation report is required and must include a determination as to whether a change in growing area classification is necessary.

The Authority is required to collect and maintain survey data and information for each growing area in a centrally located file. Experience with the sanitary survey program for determining the appropriate classification for each growing area indicates a tendency to omit or de-emphasize some components of the sanitary survey unless a central state file of all sanitary survey reports, update information, and reevaluation reports is maintained. This is particularly true when responsibility for shellfish sanitation is divided between two or more state agencies. Maintenance of a central state file also simplifies the appraisal of state programs by the FDA and prevents loss of useful historical data.

Minimum Requirements of the Sanitary Survey Report

The following outline contains the minimum requirements for the written growing area sanitary survey report required in the NSSP Model Ordinance.

- A. Executive Summary
- B. Description of Growing Area
 - (1) Location map or chart showing growing area
 - (2) Description of area and its boundaries
 - (3) History of growing area classification
 - * Date of last sanitary survey
 - * Previous classification(s) map(s)
- C. Pollution Source Survey
 - (1) Summary of Sources and Location
 - * Information gathered under the shoreline survey procedures outlined above.
 - * Map or chart showing the location of major sources of actual or potential pollution in the survey area.
 - * Table of sources of pollution cross-referenced to the survey area map.
 - (2) Identification and evaluation of pollution sources
 - * Domestic wastes (discussion and maps)

- * Storm water
 - * Agricultural waste (farms, feedlots, & slaughterhouse operations)
 - * Wildlife areas
 - * Industrial wastes
- D. Hydrographic and Meteorological Characteristics
- (1) Tides (type and amplitude), and currents (velocity and direction)
 - (2) Rainfall
 - * Amount
 - * When (e.g. time of year)
 - * Frequency of significant rainfalls
 - * Winds (Seasonality and effects on pollution dispersion)
 - (3) River discharges (volume and seasonality)
 - (4) Discussion concerning effects of pollution distribution and hydrographic factors (dilution, dispersion, and time of travel) on water quality throughout the growing area
 - * Salinity, depth, and stratification characteristics
 - * Computer model verification if used for classification.
- E. Water Quality Studies
- (1) Map of sampling stations
 - (2) Sampling plan and justification
 - * Adverse condition sampling
 - * Random sampling
 - (3) Sample Data Analysis and Presentation: Tables containing the basic NSSP statistics (number of samples, median or geometric mean, and the respective variability factors)
 - * Station by station monitoring data array collected under the adverse condition or systematic random sampling monitoring strategy
 - * Daily sampling results and number of samples collected for survey
 - * Overall compliance with NSSP criteria
 - * Sorting of data by environmental pollution condition
 - * Classification assigned to each station
- F. Interpretation of Data in Determining Classification to Be Assigned to Growing Area: A discussion of how actual or potential pollution sources, wind, tide, rainfall, etc. affect or may affect water quality, that will address the following:
- (1) Effects of meteorological and hydrographic conditions on bacterial loading
 - (2) Variability in the bacteriological data and causes
- G. Conclusions
- (1) Map or chart showing classification assigned to growing area(s) (closure lines, boundary lines separating various classifications)
 - (2) Legal description of growing area boundaries
 - (3) Management plan for growing area if in the conditionally approved or conditionally restricted classification
 - (4) Recommendations for sanitary survey improvement
 - * Changes in monitoring schedules, addition of sampling stations or station relocation, etc.
 - * Comments

Growing Area Classifications

As a result of the information gathered during the sanitary survey, the Authority should be able to distinguish those growing areas suitable for harvest of shellstock for direct human consumption, those growing areas where the shellfish will require treatment to make them safe for human consumption, and

those growing areas unsuitable to harvest for human consumption. The probable presence or absence of pathogenic microorganisms, marine biotoxin or other poisonous or deleterious substances in growing area waters is important to the Authority in deciding how the shellfish obtained from the growing area should be used. The Authority's decision, based on the sanitary survey information, will place all actual and potential growing areas in one of the five possible NSSP growing area classifications.

The five growing area classifications are approved, conditionally approved, restricted, conditionally restricted and prohibited. Except for an emergency situation such as conditions following a hurricane when a growing area in the approved classification may be placed temporarily in the closed status, a growing area in the approved classification is always in the open status. The remaining four growing area classifications all place some type of restriction on shellstock harvesting. For more information concerning the enforcement of these restrictions, see the NSSP Guidance Document, *Growing Area Patrol and Enforcement of Growing Area Restrictions* (ISSC/FDA, 2002).

Growing areas are placed in the approved classification when the sanitary survey information and marine biotoxin surveillance data indicate that fecal material, pathogenic microorganisms, poisonous, or deleterious substances are not present in the growing area in unacceptable concentrations. Shellstock harvested from these growing areas may be sold directly to the public for consumption raw or cooked.

Use of the conditionally approved and conditionally restricted classifications by the Authority is optional. The conditional classifications are designed to address growing areas that are subject to intermittent microbiological pollution. These classifications offer the Authority an alternative to placing the area in the restricted or prohibited classification year round when, during certain times of the year or under certain conditions, the shellstock from the growing area may be safely harvested. The concept also applies to situations where conditions are acceptable for harvest when wastewater treatment plant operation is satisfactory, but not when a malfunction occurs. A management plan is required that describes the controls to provide public health protection in the use of the conditional classifications. For a full explanation of the conditional classifications and their use, see the NSSP Guidance Document, *Management Plans for Growing Areas in the Conditional Classifications* (ISSC/FDA, 2002).

A growing area may be placed in the restricted classification instead of the prohibited classification when the sanitary survey indicates a limited degree of pollution. This option may be used when the sanitary survey for the growing area indicates that the levels of fecal material or poisonous or deleterious substances in the growing area are such that additional treatment through depuration or relay can render the shellstock safe for human consumption. A common situation in the use of the restricted classification occurs when a growing area is affected by non-point source pollution from either urban or rural sources. In this situation, the water quality fluctuates unpredictably or with sufficient frequency that the use of the conditionally approved classification is precluded. The Authority should use the restricted classification only when sufficient depuration or relay studies have been conducted to establish raw product quality requirements at the harvest level; and when the Authority has sufficient administrative and technical resources to properly administer this classification. These resources include monitoring of pollution sources; providing coordination between state, local and industry officials; issuing special harvesting permits; and supervising the harvesting and transport of shellstock to relay sites or depuration facilities. For a complete discussion of the supervision requirements at the harvest level, see the NSSP Guidance Document, *Shellstock Relay* (ISSC/FDA, 2002).

Use of the restricted classification requires the Authority to develop the controls necessary to assure that the shellfish are relayed or depurated prior to consumption. Bacteriological water quality standards are applied on a growing area specific basis. The criteria may vary according to the use to be made of the shellstock and the effectiveness of the relay or depuration process used to cleanse the shellstock. Process

effectiveness is determined through a study, which establishes the fecal coliform density in the shellstock at the time of harvest, and the density that can be achieved at the completion of the process. Effectiveness of the process is likely to vary between growing areas used for natural cleansing treatment in relay operations and between depuration facilities used for controlled cleansing treatment. The species of shellstock may also affect the effectiveness of the relay or depuration process. For a complete discussion of relay, see the NSSP Guidance Document, *Shellstock Relay* (ISSC/FDA, 2002).

A growing area is placed in the prohibited classification when the sanitary survey or marine biotoxin surveillance program indicates that fecal material, pathogenic microorganisms, poisonous or deleterious substances, marine biotoxin, or radionuclides may reach the harvest area in excessive concentrations. The NSSP Model Ordinance also requires that a growing area for which there is no sanitary survey be placed in the prohibited classification as a precautionary measure. Taking shellstock from a prohibited area for any human food purpose is not allowed.

Depletion of prohibited areas can be an effective deterrent to illegal harvesting as it provides a safeguard against contaminated shellfish reaching the market and eliminates a temptation for harvesters. Depletion may be more economical and effective than patrol of prohibited areas in protecting public health. In a depletion operation, all market sized shellstock and as many of the smaller sized shellstock as can be gathered by reasonable methods are removed from the growing area. To be effective, depletion operations should be conducted at sufficient intervals to keep growing areas free of commercial quantities of market-sized shellstock. When commercial harvesters conduct depletion operations, the Authority or the Patrol Authority must provide effective supervision.

The NSSP Model Ordinance also requires that an area in the prohibited classification (closed safety zone) must be established between any sewage treatment plants or other waste discharge of public health significance and any growing area placed in the approved, conditionally approved, restricted, or conditionally restricted classification. The size of the prohibited area should be based on the effectiveness and level of sewage treatment; the location of the shellstock resource that would be affected; the classification of adjacent waters, the total time it would take for the person responsible for the operation of the sewage treatment facility to detect a failure and notify the Authority; the time it would take the Authority to issue a notice to stop shellstock harvesting, and the degree of effluent dilution. Due consideration should be given to the possibility that emergency actions might be necessary on holidays or at night.

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